DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration	**APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11(c) FOR A LASER LIGHT SHOW, DISPLAY, OR DEVICE**	Form Approved: OMB No. 0910-0025 Expiration Date: December 31, 2006 See Page 4 for OMB Statement. DOCKET NUMBER

NOTE: No laser light show, projection system, or device may vary from compliance with 21 CFR 1040.11(c) in design or use without the approval of this application in accordance with 21 CFR 1010.4.

INSTRUCTIONS

1. Check all applicable boxes and type or print the requested information.
2. Submit an original and four (4) copies.
3. Mail your application to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm 1061, 5630 Fishers Lane, Rockville, MD 20852.
4. Enter docket number if assigned.

1. NAME OF COMPANY
Mezzanotte LLC

2. ADDRESS OF COMPANY *(Include ZIP Code)(If P.O. Box is used, include actual street address also.)*
168 Broadway Street Saugus, MA 01906

3. NAME AND TITLE OF RESPONSIBLE PERSON	4. TELEPHONE NO. *(Include area code)*	5. DATE OF SUBMISSION
Frank Amato Owner	(781) 231-5111	12/06/2004

6. THE APPLICANT REQUESTS THE VARIANCE TO BE IN EFFECT FOR A PERIOD OF 2 YEARS FROM THE DATE OF ISSUE. *(In general, the Agency will approve a variance for only two years. If a longer period is requested, a justification must be attached as part of the application.)*

7. **PRODUCT DESCRIPTION AND USE**

a. LIST NAME AND/OR MODEL NUMBER(S) FOR THE LASER LIGHT SHOW(S) AND PROJECTOR(S)
Lumalaser Beamburst Emerald 20

b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED
- ☐ A laser display device
- ☑ A projector for a laser light show
- ☐ A laser light show
- ☐ Other *(Specify)*_____

c. ☐ PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS

d. PRODUCT IS INTENDED FOR USE IN A
- ☐ Planetarium or other dome projection structure
- ☐ Theater
- ☐ Hotel/motel ballroom or meeting room
- ☐ Store displays
- ☐ Trade show or convention
- ☑ Discotheque or night club
- ☐ Pavilion
- ☐ Indoor arena
- ☐ Outdoor arena
- ☐ Museum
- ☐ Outdoor unenclosed area
- ☐ Other *(Specify)*_____

e. PRODUCT IS INTENDED TO BE USED
- ☑ At only one *(Fixed)* location
- ☐ At a variety of *(Tour)* locations
- ☐ Other *(Specify)*_____

f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION
- ☑ More than 15 days
- ☐ More than 5 but not more than 15 days
- ☐ Less than 5 days

g. TOUR IS INTENDED TO RUN FOR
- ☐ More than 6 months
- ☐ 1-6 months
- ☐ Less than one month
- ☑ Not applicable *(Not a tour)*
- ☐ Other *(Specify)*_____

h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS
- ☐ Front screen projections
- ☐ Rear screen projections
- ☐ Holographic displays
- ☐ Multiple reflection/diffraction effects
- ☐ Audience scanning *(Also includes scanning any accessible uncontrolled areas)*
- ☐ Reflections from stationary mirrors or mirrored surfaces *(Beam Matrices)*
- ☐ Stationary irradiation of rotating mirror balls, etc.
- ☐ Scanning irradiation of rotating mirror balls, etc.
- ☐ Fiber optic projections
- ☐ Fog, smoke, or other scattering enhancement effects
- ☑ Other *(Specify)* projecting upward into a flat black ceiling

8. **LASER RADIATION LEVELS**

LASER MEDIUM *(Ar, He-Ne, etc.)*	WAVE LENGTHS *(nm)*	PEAK POWER *(watts)*
	532 nm	20 mW
		1/50 watt

9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE

10. REASON FOR REQUESTING VARIANCE
- ☑ Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible
- ☐ Other or additional explanation *(Specify)*_____

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11. MANNER IN WHICH IT IS PROPOSED TO DEVIATE FROM THE REQUIREMENTS OF THE APPLICABLE STANDARD

☑ It is proposed to deviate from the provisions of 21 CFR 1040.11(c) in that the accessible emission level would exceed the accessible emission limits specified in 21 CFR 1040.11(c).

☐ It is proposed to deviate from the provisions of 21 CFR 1040.11(c) as follows:

12. ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION

☑ Laser light shows and displays are accepted popular media in entertainment and the arts. Use of power levels in excess of the limits imposed by 21 CFR 1040.11(c) is necessary to achieve the required effects in these media.

☐ Other or additional advantages *(describe and explain)*.

13. EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. *(Check as many boxes as apply. In item 14 "Remarks," justify any boxes not checked, using additional sheets as necessary. State any other means of radiation protection that will be used.)*

a. ☑ All laser products, systems, shows, and projectors will be certified to comply with 21 CFR 1040.10 and the conditions of this variance and will be reported as required by 21 CFR 1002.10 AND 1002.11 using the reporting guides provided for such purpose. These actions will be accomplished prior to any introduction into commerce.

b. ☑ Effects not specifically indicated in this variance application will not be performed. No other effects will be added until an amendment to the variance has been obtained and the required reports or supplements, as applicable, have been submitted.

c. ☑ Scanning, projection, or reflection of laser and collateral radiation *(Light show radiation)* into audience or other accessible uncontrolled areas will not be permitted except for diffuse reflections produced by the atmosphere, added atmospheric scattering media, and target screens.

d. ☑ Laser radiation levels in excess of the limits of Class I will not be permitted at any point less than 3.0 meters above any surface upon which persons other than operators, performers, or employees are permitted to stand or 2.5 meters below or in lateral separation from any place where such persons are permitted to be. Operators, performers, and employees will not be required or allowed to view radiation above the limits of Class I or be exposed to radiation above the limits specified in 21 CFR 1040.11(c).

e. ☑ Any product which relies on scanning to meet access, exposure, or product class limits will incorporate a scanning safeguard system which directly senses scanner motion and which will react fast enough to preclude exceeding the applicable limit.

f. ☑ All laser light shows shall be under the direct and personal control of trained, competent operator(s). The operator(s) will:

(1) Be an employee of the variance holder who will be responsible for the training and the conduct of the operator;

(2) Be located where all beam paths can be directly observed at all times; and

(3) Immediately terminate the emission of light show radiation in the event of any unsafe condition; or, for outdoor shows, upon request by any air traffic control officials.

g. ☑ The maximum laser projector output power will not exceed the level required to obtain the intended effects.

h. ☑ The projection system *(i.e., the projector and all other components used to produce the lighting effects)* will be securely mounted or immobilized to prevent unintended movement or misalignment. Beam masking will be provided as an inherent part of the system design to prevent overfilling of screens, beam stops, targets, etc.

i. ☑ Laser projectors will not be delivered to any other party under an agreement of sale, lease, or loan unless and until the recipient demonstrates that they have a variance in effect at the time of delivery that permits them to produce laser light shows incorporating such projector(s).

j. ☑ In addition to the requirements of 21 CFR 1040.10(h), the manufacturer of laser projectors/systems will provide to parties who purchase, lease, or borrow the equipment, adequate users' instructions for safe installation and operation which explain the responsibility of the recipient as an independent light show manufacturer to submit the required reports and apply for and obtain a variance from CDRH prior to introduction into commerce of any laser light shows.

k. ☑ The requirements of 21 CFR 1002.30(a)(1) and (2) will be accomplished through the use of written procedures for setup, alignment, testing, and performance of each show. These procedures will be in sufficient detail to ensure compliance with 21 CFR 1040.10, the conditions of this variance, and the control of access to radiation areas using the procedures described in the ANSIZ136.1 standard for the safe use of lasers *(American National Standards Institute, 1430 Broadway, New York, NY 10018)* or any other equivalent user consensus standard and, where applicable, state or local requirements. Laser radiation areas which can contain radiation levels above the limits specified in 21 CFR 1040.11(c) will be clearly identified by the posting of warning signs and/or restricting access through physical means *(such as pressure switches, photo cells, barriers, guards, etc.)*. These requirements apply to temporary areas *(such as during set up and alignment procedures)* and to final or permanent areas. The variance holder will retain the records of these procedures and the results of all tests as required by 21 CFR 1002.31. A copy of the variance application, the approval letter, current procedures, and records relating to each particular show will be with the operator or other responsible individual and will be made available for inspection by FDA and other responsible authorities.

l. ☐ Advance written notification will be made as early as possible to appropriate federal, state, and local authorities providing show itinerary with dates and locations clearly and completely identified, and a basic description of the proposed effects including a statement of the maximum power output intended. Such notifications will be made, but not necessarily be limited, to:

(1) The Center for Devices and Radiological Health, Office of Compliance (HFZ-342), 2098 Gaither Road, Rockville, MD 20850, providing the initial and closing dates for fixed installations and the itinerary for mobile shows. In addition, unless all aspects of each show have been reported and accession numbers clearly referenced, each notice will include detailed descriptions of each show and a listing of all effects to be performed in sufficient detail to confirm compliance with the regulations and this variance.

(2) The Federal Aviation Administration (FAA) for any projections into open airspace at any time *(i.e., including set up, alignment, rehearsals, performances, etc.)*. If the FAA objects to any laser effects, the objections will be resolved and any conditions requested by FAA will be adhered to. If these conditions cannot be met, the objectionable effects will be deleted from the show

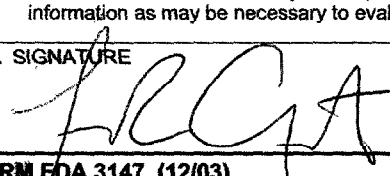
(3) State and local radiation control offices/agencies for all shows to be performed within their jurisdictions. All requirements of state and local law will be satisfied and any objections raised by local authorities will be resolved or the effects deleted. *(A list of federal and state offices is available from the Center for Devices and Radiological Health upon request.)*

14. REMARKS

Letter l -- has not been checked because the laser is being used in a permanent installation, not for touring.

CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete, and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading or incorrect in any material way. I have submitted and will submit all reports required by 21 CFR 1002.10 and 1002.11 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Center for Devices and Radiological Health, to supply such other information as may be necessary to evaluate and act on this application.

15. SIGNATURE	16. NAME *(Type or Print)*	17. TITLE
	Frank Amato	Owner